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Standardised profiling for tinnitus research

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Technical note

Standardised profiling for tinnitus research: The European School for Interdisciplinary Tinnitus Research Screening Questionnaire (ESIT-SQ)



Eleni Genitsaridi ^{a, b, *}, Marta Partyka ^c, Silvano Gallus ^d, Jose A. Lopez-Escamez ^{e, f}, Martin Schecklmann ^g, Marzena Mielczarek ^h, Natalia Trpchevska ⁱ, Jose L. Santacruz ^j, Stefan Schoisswohl ^g, Constanze Riha ^k, Matheus Lourenco ^l, Roshni Biswas ^{a, b, d}, Nuwan Liyanage ^m, Christopher R. Cederroth ⁱ, Patricia Perez-Carpena ^{e, n}, Jana Devos ^{o, p}, Thomas Fuller ^l, Niklas K. Edvall ⁱ, Matilda Prada Hellberg ⁱ, Alessia D'Antonio ^q, Stefania Gerevini ^r, Magdalena Sereda ^{a, b}, Andreas Rein ^s, Theodore Kypraios ^t, Derek J. Hoare ^{a, b}, Alain Londero ^u, Rüdiger Pryss ^v, Winfried Schlee ^g, Deborah A. Hall ^{a, b, w, x}

^a NIHR Nottingham Biomedical Research Centre, 113 The Ropewalk, Nottingham, NG1 5DU, UK

^b Hearing Sciences, Division of Clinical Neuroscience, School of Medicine, University of Nottingham, Building 40 University Park, Nottingham, NG7 2RD, UK

^c Centre for Cognitive Neuroscience, Division of Physiological Psychology, University of Salzburg, Hellbrunnerstraße 34, 5020, Salzburg, Austria

^d Department of Environmental Health Sciences, Istituto di Ricerche Farmacologiche Mario Negri IRCCS, Via G. La Masa 19, 20156, Milan, Italy

^e Otolaryngology & Neurotology Group CTS495, Department of Genomic Medicine- Centro de Genómica e Investigación Oncológica – Pfizer/Universidad de Granada, Junta de Andalucía (GENYO), Avda de la Ilustración, 114 18016, Granada, Spain

^f Department of Otolaryngology, Instituto de Investigación Biosanitaria ibs.GRANADA, Hospital Universitario Virgen de las Nieves, Avda. de las Fuerzas Armadas, 2 18014, Granada, Spain

^g Department of Psychiatry and Psychotherapy, University of Regensburg, Universitaetsstr. 84, 93053, Regensburg, Germany

^h Department of Otolaryngology, Laryngological Oncology, Audiology and Phoniatics, Medical University of Lodz, 113 Zeromskiego St., 90-549, Lodz, Poland

ⁱ Experimental Audiology, Department of Physiology and Pharmacology, Biomedicum, Karolinska Institutet, Solnavägen 9, 171 65, Stockholm, Sweden

^j Department of Otorhinolaryngology (ENT), University Medical Center Groningen (UMCG), Hanzplein 1, 9700 RB, Groningen, the Netherlands

^k Department of Neuropsychology, University of Zurich, Binzmuehlestr. 14/25, 8050, Zurich, Switzerland

^l Department of Clinical Psychological Science, Faculty of Psychology and Neuroscience, Maastricht University, Universiteitssingel 40, 6229, ER, Maastricht, the Netherlands

^m University of Zurich, University Hospital Zurich, Department of Otorhinolaryngology, Head and Neck Surgery, Frauenklinikstrasse 24, 8091, Zurich, Switzerland

ⁿ Department of Otolaryngology, Hospital Universitario San Cecilio (Campus de la Salud), Instituto Biosanitario de Granada, ibs.Granada, Avda de la Investigación S/n, 18016, Granada, Spain

^o Department of Neuroscience, School for Mental Health and Neuroscience, Maastricht University Medical Center, Universiteitssingel 40, 6229 ER, Maastricht, the Netherlands

^p Department of Ear Nose and Throat/Head and Neck Surgery, Maastricht University Medical Center, Universiteitssingel 40, 6229, ER, Maastricht, the Netherlands

^q Department of Public Health, IRCCS, Istituto di Ricerche Farmacologiche “Mario Negri”, Via G. La Masa 19, 20156, Milan, Italy

^r Bocconi University, Via Roentgen 1, 20136, Milan, Italy

^s Andreas Rein Engineering, Elisabethenstr. 28, 89077, Ulm, Germany

^t School of Mathematical Sciences, University of Nottingham, NG7 2RD, Nottingham, UK

^u Service ORL et CCF, Consultation Acouphène et Hyperacousie, Hôpital Européen G. Pompidou, 20, Rue Leblanc, 75015, Paris, France

^v Institute of Databases and Information Systems, Ulm University, James-Franck-Ring, 89081, Ulm, Germany

^w Nottingham University Hospitals NHS Trust, Queens Medical Centre, Derby Road, Nottingham, NG7 2UH, UK

^x University of Nottingham Malaysia, Jalan Broga, 43500, Semenyih, Selangor Darul Ehsan, Malaysia

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ABSTRACT

Background: The heterogeneity of tinnitus is substantial. Its numerous pathophysiological mechanisms and clinical manifestations have hampered fundamental and treatment research significantly. A decade ago, the Tinnitus Research Initiative introduced the Tinnitus Sample Case History Questionnaire, a case

* Corresponding author. Hearing Sciences, Division of Clinical Neuroscience, School of Medicine, University of Nottingham, Building 40 University Park, Nottingham, NG7 2RD, UK.

E-mail addresses: eleni.genitsaridi@nottingham.ac.uk, mzxe1@nottingham.ac.uk (E. Genitsaridi).

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history instrument for standardised collection of information about the characteristics of the tinnitus patient. Since then, a number of studies have been published which characterise individuals and groups using data collected with this questionnaire. However, its use has been restricted to a clinical setting and to the evaluation of people with tinnitus only. In addition, it is limited in the ability to capture relevant comorbidities and evaluate their temporal relationship with tinnitus.

Method: Here we present a new case history instrument which is comprehensive in scope and can be answered by people with and without tinnitus alike. This 'European School for Interdisciplinary Tinnitus Research Screening Questionnaire' (ESIT-SQ) was developed with specific attention to questions about potential risk factors for tinnitus (including demographics, lifestyle, general medical and otological histories), and tinnitus characteristics (including perceptual characteristics, modulating factors, and associations with co-existing conditions). It was first developed in English, then translated into Dutch, German, Italian, Polish, Spanish, and Swedish, thus having broad applicability and supporting international collaboration.

Conclusions: With respect to better understanding tinnitus profiles, we anticipate the ESIT-SQ to be a starting point for comprehensive multi-variate analyses of tinnitus. Data collected with the ESIT-SQ can allow establishment of patterns that distinguish tinnitus from non-tinnitus, and definition of common sets of tinnitus characteristics which might be indicated by the presence of otological or comorbid systemic diseases for which tinnitus is a known symptom.

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1. Introduction

Tinnitus is a common physiological condition that can have a negative impact on the affected individual in multiple domains of everyday life (Tyler and Baker, 1983; Sanchez and Stephens, 1997; Watts et al., 2018). It is well known that there is no objective diagnostic measurement for tinnitus, and as a consequence, patient assessment relies on self-report. Perhaps less well known is how wide-ranging self-reported symptomatology can be from one individual to another. For example, a recent review of 86 studies, analysing data collected from 16,381 patients, identified 42 discrete complaints, which spanned physical and psychological health, quality of life, and negative attributes of the tinnitus sound (Hall et al., 2018a). No single self-report instrument captures all this diversity, and this poses challenges for characterising tinnitus based on an individual's lived experience, both for research and for clinical practice. Another challenge is that individuals with tinnitus might not form clearly delineated (i.e. distinct) subgroups sharing the same symptomatology, but rather that patient characteristics might fall along various continua which can contribute towards a profile across multiple domains (van den Berge et al., 2017). Given this distinction, henceforth we use the term 'subtyping' when referring to the identification of subgroups as distinct categories of tinnitus, and the term 'profiling' when referring to the characterisation of individual patients based on the distribution pattern of symptoms along a continuum (or multiple continua).

One of the main risk factors for tinnitus is hearing loss (Nicolas-Puel et al., 2002; Henry et al., 2005; Norena, 2011). Hearing loss occurs due to many different otological disorders, ranging from a benign problem such as impacted earwax, to more severe conditions such as vestibular schwannoma or Ménière's disease (Lopez-Escamez et al., 2015). However, tinnitus is also associated with non-otological medical conditions such as depression or diabetes (Baguley et al., 2013). The link between tinnitus and underlying pathological mechanisms is largely unknown (e.g. Haider et al., 2018). Different mechanisms might be responsible for different aspects of tinnitus, e.g. presence or severity (Hebert et al., 2012; De Ridder et al., 2014). Complexity increases because the same pathology can have largely different clinical presentations and natural history. Knowledge to predict such variations is lacking. These scientific uncertainties hinder the identification of different pathophysiological forms of tinnitus, which would in turn allow the development of treatments according to classifications (Tyler et al.,

2008; Haider et al., 2018).

Hitherto tinnitus profiling has typically been conducted by exploring associations between demographic variables, self-reported symptomatology, aetiological indicators, and psychological and audiological measures (Hallam et al., 1984; Ward et al., 2015; Hoekstra et al., 2014; Heijneman et al., 2013; Norena et al., 1999). Numerous tinnitus profiling frameworks have been proposed (Hemming, 1880; Jones et al., 1890; Goodhill, 1950; Nodar, 1978, 1996; Evered and Lawrenson, 1981; Dauman et al., 1991; Shulman, 1991; Zenner, 1998; Jastreboff and Hazell, 2004; Langguth et al., 2011; Tunkel et al., 2014; Cianfrone et al., 2015; Levine and Oron, 2015; Henry, 2016), but a universally endorsed classification system is yet to be developed. Given the high dimensionality of tinnitus, it has long been recognised that advances in the profiling of tinnitus require large-scale data collection with many hundreds or thousands of individuals in order to identify common patterns of aetiology and/or symptomatology among numerous variables (Meikle and Griest, 1989; Landgrebe et al., 2010).

Irrespective of whether the intended purpose is to facilitate tinnitus subtyping or profiling, a number of data repositories have been created by individual clinics or research centres such as the Tinnitus Data Registry (Oregon Hearing Research Centre) and the Swedish Tinnitus Outreach Project (Karolinska Institutet). Multi-national, multi-centre data repositories for tinnitus would provide greater leverage to addressing these scientific issues, but they are rare. The Tinnitus Research Initiative (TRI) database is unique in that it includes data from many centres around the world, collected according to a standardised protocol (Landgrebe et al., 2010).

Within the TRI database project, the Tinnitus Sample Case History Questionnaire (TSCHQ) is an important instrument, used for the standardised collection of information regarding patient demographics, tinnitus history, tinnitus characteristics and modulating factors, and comorbidities. The items in the TSCHQ are based on 'a considerable variety of case history questionnaires' and were developed as part of a consensus for tinnitus patient assessment (Langguth et al., 2007, p. 529). The TSCHQ is the mainstay of subtyping analyses using the TRI database (Kreuzer et al., 2012; Vielsmeier et al., 2012, 2015; Schecklmann et al., 2014; Langguth et al., 2017a, 2017b) and has even been adopted for independent studies not involving the TRI database project (Kojima et al., 2017; Ward et al., 2015). It has therefore been a valuable tool to the tinnitus research community. However, it includes only a few questions about co-existing medical conditions and is, therefore,

not suitable for acquiring information about the tinnitus-relevant medical history (e.g. presence of otological or tinnitus-related comorbid systemic diseases, history of medical treatments that can cause tinnitus).

Inspired by preceding projects and the importance of big-data analysis for profiling tinnitus, a new tinnitus-oriented database has been developed, namely the European School for Interdisciplinary Tinnitus Research (ESIT) database (Schlee et al., 2017; European School for Interdisciplinary Tinnitus Research, 2018). One of the main objectives of the ESIT project is to contribute to our understanding of tinnitus heterogeneity and to create a tinnitus profiling framework. Towards this aim, data from the population will be collected using standardised measures across the different projects in order to create a large multinational database. The ESIT Screening Questionnaire (ESIT-SQ) is a self-reported tinnitus-relevant history questionnaire for standardised collection of information from both tinnitus and non-tinnitus populations that has been created for this purpose. It was developed with specific attention to the breadth of questions about potential risk factors for tinnitus, and characteristics of tinnitus.

In this technical note, we present the rationale and the methodology for the development of ESIT-SQ. This questionnaire was originally created in English and subsequently translated into six languages (Dutch, German, Italian, Polish, Spanish, and Swedish). Languages were chosen based on the needs of the ESIT projects conducted across 12 European cities (European School for Interdisciplinary Tinnitus Research, 2017). Paper and pencil versions of the ESIT-SQ are provided in all languages as supplementary material (B–H).

2. Rationale

The rationale for developing a new tinnitus-specific case history instrument was the lack of a detailed structured questionnaire for both screening and profiling tinnitus. Such a questionnaire is an important tool for research because it could enable collection of large-scale datasets for characterising tinnitus heterogeneity and tinnitus aetiology.

The ESIT-SQ was developed with two main objectives. The first objective was to create a questionnaire that would allow standardised data collection from the entire adult population, tinnitus and non-tinnitus, which are essential for investigating mechanisms associated with tinnitus. Although there are numerous case history questionnaires for tinnitus patients (Stouffer and Tyler, 1990; Langguth et al., 2007; Schechter and Henry, 2002), we are not aware of any that use common questions for both tinnitus and non-tinnitus populations. For example, the TRI database contains data only from a clinical sample of tinnitus patients and therefore the TSCHQ starts from the basis that the respondent has tinnitus. To address this limitation, the ESIT-SQ is structured in a way that it can be answered by anyone, irrespective of whether or not they have tinnitus.

The second objective was to create a detailed instrument for profiling the tinnitus population, considering other relevant case history questionnaires and according to the opinion of researchers within the ESIT consortium. Careful consideration was given to potential risk factors for tinnitus (e.g. demographics, lifestyle, and general medical and otological histories) and tinnitus characteristics (e.g. perceptual characteristics, modulating factors and associations with co-existing conditions). Examples of questions that are important for tinnitus profiling but are not commonly included in history questionnaires are the history of medical treatments that can cause tinnitus (e.g. ear surgery, neurosurgery, or chemotherapy) and the temporal associations between co-existing conditions and tinnitus onset. It would be preferable to collect such medical

history information using interview methods. However, self-reported questions, although not ideal, are the only way to provide additional explanatory leverage with large-scale datasets.

3. Description of the methods

3.1. ESIT-SQ development

Various sources were consulted to create an initial set of potential questions and response options for peer review. Source questions were modified, as deemed appropriate. Sources included the TSCHQ and an unpublished case history questionnaire (in French) previously developed by one of the co-authors (AL) who is a consultant otologist specialising in tinnitus. This latter questionnaire is currently being used at the Georges Pompidou tinnitus and hyperacusis clinic (Paris) and contains a comprehensive set of items that have diagnostic utility. It was developed for self-completion, enabling the patients to complete it before the first appointment. It is used to facilitate the first medical interview during which the healthcare practitioner has a short time window to establish a positive relationship with a patient, make an accurate diagnosis, and plan an efficient therapeutic intervention. We used the latest version of this questionnaire created in 2010 that includes some items from the TSCHQ. After translating it into English, we adapted and included many questions on medical and tinnitus history. In addition, we included questions on self-reported body measurements and level of education adapted from the European Tinnitus Survey (unpublished), and questions on smoking and alcohol which were translated, simplified, and adapted from a survey on smoking conducted annually in Italy by a market research company (Gallus et al., 2015; Ascitto et al., 2015; Lugo et al., 2015). Such variables are known risk factors for tinnitus (Martines et al., 2015; Shargorodsky et al., 2010; Kim et al., 2015). What is more, because there are genetic factors that may contribute to tinnitus (Lopez-Escamez et al., 2016; Maas et al., 2017; Cederroth et al., 2019), we included a question on familial history of tinnitus and hearing loss. It is worth noting that the initial set of questions did not include specific questions about the functional impact of tinnitus on the individual because this can be assessed using existing tools.

Peer review of the initial list of 42 questions was invited from ESIT collaborators (15 early-career researchers and 19 experienced researchers). Based on their feedback, items were modified and circulated for a second round of consultation and modification. At the end of this process, 39 questions for the ESIT-SQ were finalised, and an additional set of 17 optional questions was created. Additional items were not deemed essential for profiling, but they were offered as optional. The sources for all items in the ESIT-SQ and for the optional questions are shown in Supplementary Material A.

After finalising questions and response options, two administration formats were generated in English; an electronic version and a paper and pencil version. Both versions are available (see section 4.1). Questions and response options are the same across formats; the difference being that in the electronic version, questions that are contingent on preceding responses are generated automatically. The content of the ESIT-SQ items are reported in the Results section.

3.2. Translation into six languages

All items required for the two administration formats of the ESIT-SQ were translated into Dutch, German, Italian, Polish, Spanish, and Swedish, for mainland Netherlands, Germany, Italy, Poland, Spain, and Sweden respectively. A translation plan was designed to guide all translations based on available resources and the recently published good practice guide for translating and adapting hearing-

related questionnaires (Hall et al., 2018b). Due to time and budget constraints, the translation process reported here was limited to three of the six recommended steps (steps 1, 2 and 6). Back translation, committee review and field testing are advised as future steps in order to evaluate the functional equivalence between the translated versions proposed here and the original English language source.

The primary developer (EG) first created concept descriptions for all questions and response options to help translators maintain the concept and semantic equivalence with the original English version. Each translation was coordinated by a nominated co-author. Each translation coordinator first appointed three native speakers of the target language who were also proficient in English and had lived in the target country. These were not professional translators, but they were all educated to university level. For the German translation, one translator was a German native speaker and two were Austrian-German native speakers. For the Dutch translation, two translators were Dutch native speakers and one translator was a Belgian-Dutch native speaker. Coordinators provided each translator with background information about the ESIT-SQ (e.g. purpose and target population) and the requirements of the translation. Two translators produced independent forward translations which the third consolidated into a single harmonised version, in consultation with the two translators when appropriate. Providing a common brief and involving three native speakers in this way promoted a translated version that matched the source language version and used natural wording suited to the target population. The coordinators and translators, and three more German native speakers for the German translation, confirmed this objective was met and proofread the documents for grammatical and spelling errors.

3.3. Data handling and data quality of the ESIT-SQ implementation in the ESIT database

For projects that are part of the ESIT, data collected using the ESIT-SQ are stored in the ESIT database. The first step taken to ensure high-quality data was to implement the user interface using standardised input fields that can be used to assist and restrict user input where reasonable. One example is the use of standardised inputs for integral values that will report ill-formed input to the user automatically. Whenever a participant decides to save their current progress, the data will be validated on the server side and the results will be reported to the user in various ways. For every validation error, the corresponding question will be highlighted and the part that includes the error will be indicated. The overall state of data entry will be indicated with localised status messages and textual instructions. Within the internal section of the database, the staff can monitor and review data entry and export the data when needed. Authorised staff can configure custom selection criteria depending on analysis or study requirements. For example, the data export can be configured to exclude datasets that are not fully validated, are missing certain items, or meet other criteria for exclusion. All data are stored in a central database that only authorised personal are granted access to. A role management system is used to enforce different levels of data access. Centre Editors can view and edit individual patient datasets of their respective centre and Centre Experts can additionally export data of all the patients of their centre, for data analysis. Centre Administrators have all rights as the Centre Editors and Centre Experts and can additionally invite or remove staff members. Staff members that need access to the database receive a password protected user account with a role according to their "Need to know". In general, researchers can only see the data of their own centre.

The standardised data assessment and storage in the ESIT

database allows efficient multi-centre data analysis of the participating partners. Such analyses are only done with anonymised datasets. Multi-centre analyses include only data from centres participating in the respective analysis.

The database does not store personal information like names, addresses, phone numbers, e-mail addresses, or IP addresses that can be used to identify a certain participant directly. There is a unique identifier that can be used to link and combine data from different sources and the staff can assign a custom external identifier to a participant. The systems storing personal information of a certain patient are maintained exclusively within the local centre(s) that need to identify a patient individually. If a participant can be identified individually, e.g. by the value of the external identifier attribute, and requests for their data to be anonymised or deleted according to the rules set by the General Data Protection Regulation (GDPR), the database administrative staff will, in accordance with the patient's centre(s), anonymise or delete the participants data permanently.

The ESIT database is physically located at the Institute of Databases and Information Systems (DBIS) at the University of Ulm, Germany. A backup of the database is performed every night for data security reasons whereby the database is backed up to a server hosted by the Strato AG (Berlin, Germany) and to a second server located at the DBIS institute. All server are located in Germany. A Secure Sockets Layer (SSL) protocol is used for all data transfers.

4. Results and discussion

4.1. Overview of the ESIT-SQ

The ESIT-SQ consists of 39 closed, mainly multiple choice, questions (Supplementary Material B). It is structured in two parts. Part A includes 17 questions that can be answered by everyone irrespective of whether or not they have tinnitus. Seven questions ask about demographics, body characteristics, education and lifestyle, one question asks about family history, and nine questions ask about medical history and presence of hearing-related and other symptoms. The last of these questions screens for presence of tinnitus lasting for more than five minutes over the past year. Participants that respond 'yes' to this question are prompted to answer 22 more tinnitus-related questions in Part B. These include eight questions about tinnitus perceptual characteristics, one general question about the impact of tinnitus, six questions about onset-related characteristics, four questions about tinnitus modulating factors and associations with co-existing conditions, one question on objective tinnitus, and two healthcare-related questions.

The paper and pencil versions of the ESIT-SQ in English, Dutch, German, Italian, Polish, Spanish, and Swedish are provided as Supplementary Material B, C, D, E, F, G and H, respectively. The electronic version of the ESIT-SQ is embedded in the ESIT database and is available for anyone that is willing to contribute the acquired data to the ESIT database. Information on how to participate can be found on the homepage of the ESIT database (European School for Interdisciplinary Tinnitus Research, 2018).

Having the option of a paper version is important for those people without access to a home computer or a tablet, but the electronic version has a number of advantages, such as including adaptive testing or automated data validation. For example, question B8 (Supplementary Material B) asks participants suffering from other conditions such as pain syndromes, vertigo, or other ear diseases, to assess the temporal relationship between the onset of these conditions and tinnitus. In the electronic version, adaptive testing allows automatic generation of the relevant items according to preceding responses. This feature improves usability and allows

participants to navigate the questionnaire more efficiently. With regard to automated data validation, the participants' input will be validated whenever they save current progress. Participant will be informed about the validation results and asked to provide responses to all mandatory questions. Investigators can monitor the current state of data entry and review a participant's responses from an internal section of the database. In addition, the automatic upload to the database saves staff resources required for transcribing the responses from a paper version to the database, which in turn also decreases the risk of transcription errors. These and other measures were designed to improve data quality.

The ESIT-SQ is a freely available instrument for the research community, but reference should be given to this article when an author publishes data obtained using this questionnaire. Translation of the ESIT-SQ into other languages could be a further useful step to broaden the utility of this participant history questionnaire. Any additional translations and/or any revised versions of ESIT-SQ will be made available on the website of the ESIT project ([European School for Interdisciplinary Tinnitus Research, 2017](#)).

4.2. Strengths and limitations

The ESIT-SQ was designed with specific emphasis on collecting profiling-relevant information. It incorporates important items that are included in other published tinnitus history questionnaire (e.g. characteristics of the tinnitus perception) as well as novel items which are not (e.g. otological history, temporal association between tinnitus and co-existing conditions) ([Stouffer and Tyler, 1990](#); [Langguth et al., 2007](#); [Schechter and Henry, 2002](#)). These additional questions are important because a number of general medical and otological conditions can be associated with tinnitus, potentially as causal factors ([Levine and Oron, 2015](#); [Baguley et al., 2013](#)). Temporal associations between onset of tinnitus and other co-existing general medical and otological conditions have also been suggested as important for profiling tinnitus. For example, [Hallam et al. \(1984\)](#) found that coincidence of tinnitus onset with hearing loss was characteristic for a subgroup of tinnitus patients identified with cluster analysis. In addition, it has recently been suggested that temporal coincidence of onset (or aggravation) of tinnitus and somatic symptoms are important criteria for defining somatosensory tinnitus ([Sanchez and Rocha, 2011](#); [Michiels et al., 2017, 2018](#)). The ESIT-SQ screens for the presence of many of these co-existing conditions, including otological and somatic conditions, and subsequently asks for their time of onset related to the onset of tinnitus.

In addition, the ESIT-SQ is structured in such a way that everyone, regardless of having tinnitus or not, can answer it. It is, therefore, a 'free of the clinic', general purpose tool suitable for both screening for and profiling tinnitus. An electronic version of the questionnaire, along with the paper and pencil version, will enable more efficient administration in different research and clinical settings and takes advantage of data collection using various electronic devices ([Ryan et al., 2002](#); [Richter et al., 2008](#)).

The ESIT-SQ does have limitations. First, for co-existing conditions such as otological comorbidities, somatic disorders and headaches, a clinical evaluation would be preferable to patient report because it would provide more reliable information. For example, recently suggested diagnostic criteria for somatic tinnitus require physical manipulations ([Michiels et al., 2018](#)) and the diagnostic criteria for Ménière's disease require a demonstration of a temporal association of vertigo with a sensorineural hearing loss by an audiogram ([Lopez-Escamez et al., 2015](#)). Second, the need to maintain a relatively short questionnaire required a trade-off against including more questions. Therefore, questions about individual characteristics that cannot be accurately captured by one

or a few questions are not included. Such characteristics that have been shown to be associated with tinnitus include history of noise exposure, personality traits, and coping strategies. For these aspects, there are specifically developed questionnaires that can be used alongside the ESIT-SQ. Third, items included in ESIT-SQ are based on clinical expert opinion and available scientific evidence. Nevertheless, not every included variable has been demonstrated to be important for tinnitus profiling. This needs to be investigated by collecting and analysing data using this tool, and underlines the importance of updating questionnaires based on current knowledge. Finally, before widespread application of the translated versions in Dutch, German, Italian, Polish, Spanish, and Swedish, field testing step is one of the steps advised by the good practice guide ([Hall et al., 2018b](#)). Field testing describes the process whereby bilingual speakers summarise their interpretation of each translated question and response option in their own words (in English), note words or phrases that are either difficult to understand or that might sound awkward colloquially, and provide any recommendations that would make it more culturally appropriate or more acceptable to the general public. Field testing can increase confidence that the translated questions and response options are understood by the target population in the same way as the source English language version, or can identify where further improvements could be made.

5. Conclusions

Traditionally, tinnitus subtyping or profiling has been based on clinical experience, and this approach has been useful in developing frameworks to guide tinnitus assessment and management. It is now important, however, to go one step beyond and design projects that take advantage of technological advances. Combining clinical expertise with analysis of big datasets from well-designed, tinnitus-specific databases can help answer long-standing questions about tinnitus, such as which are the most important variables for tinnitus profiling and/or subtyping. The ESIT-SQ aims to contribute to such efforts by enabling standardised multinational collection of tinnitus-relevant data. It was developed to fill the gap of a self-report research tool suitable for both screening for and profiling tinnitus. Building on previous efforts, a set of 39 tinnitus-relevant items has been developed in English and translated following a common methodology to six more languages (Dutch, German, Italian, Polish, Spanish, and Swedish).

Declaration of conflicting interests

All authors declare that there is no conflict of interest.

Authors contributions

DAH, WS, EG, MP, AL, JALE, SGa, MS, DJH, NT, NL, MM and TK contributed to the development of the English version of the ESIT-SQ. DAH and EG designed the methodology for ESIT-SQ translations. JLS, JALE, and PPC contributed to the translation of ESIT-SQ in Spanish. SS, CR, and MS contributed to the translation of ESIT-SQ in German. ML, TF and JD contributed to the translation of ESIT-SQ in Dutch. RB, ADA, SGe and SGa contributed to the translation of ESIT-SQ in Italian. MP, MSe and MM contributed to the translation of ESIT-SQ in Polish. NT, NKE, MPH, and CRC contributed to the translation of ESIT-SQ in Swedish. AR, RP, and WS contributed to the development of the electronic version of ESIT-SQ. All authors contributed to manuscript development and approved the final document.

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Appendix A. Supplementary data

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